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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,784	01/22/2004	Winthrop D. Childers	200314403-1	6122

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FORT COLLINS, CO 80527-2400

EXAMINER
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DIRAMIO, JACQUELINE A

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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03/19/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/762,784	<b>Applicant(s)</b> CHILDERS ET AL.	
	<b>Examiner</b> Jacqueline DiRamio	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/22/04; 4/20/05; 11/30/07</u> .                              | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, claims 1 – 10 and 18 – 20, in the reply filed on December 27, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11 – 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Figure 8 includes reference number "320," however, this reference number is not disclosed within the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be

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labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 4, 6, 7, and 18 – 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Groll (US 2005/0019953).

Groll teaches a disposable blood test strip (device) comprising:

a substrate configured for carrying a chemical reagent; and

circuitry formed on the substrate, the circuitry comprising:

a measurement (sensor) portion associated with the chemical reagent to enable measurement of the presence and a concentration of a blood analyte; and

an information storage portion configured to store information indicative of a property of the chemical reagent (see Figures 1-4 and 10-15; and paragraphs [0010],

[0011], [0014], [0035], [0036], [0038], [0039], [0041], [0047], [0061], [0064]-[0066], [0070], [0075]-[0084], and [0094]).

With respect to Applicant's claim 2, an input and output arrangement is formed on the substrate and in electrical communication with the information storage portion to enable a meter to access information from the information storage portion for calibrating the meter (see paragraphs [0064]-[0070]).

With respect to Applicant's claim 3, the information storage portion is electrically connected to a portion of the measurement portion of the circuitry, and includes at least one electrically conductive element having an electrical characteristic that is indicative of the property of the chemical reagent (see paragraph [0014]).

With respect to Applicant's claims 4, 6, and 19, the at least one electrically conductive element comprises a plurality electrically conductive elements wherein each element is configured to be physically altered, such as via etching, and the number of altered elements produces an electrical characteristic that is indicative of the property of the chemical reagent (see paragraphs [0014], [0039], [0041], [0042], [0045], and [0075]-[0084]).

With respect to Applicant's claim 7, the test device can comprise a set of test devices with the information storage portion of each test device storing substantially the same information (see paragraphs [0012], [0066] and [0070]).

With respect to Applicant's claim 18, the limitations of this claim are discussed above with respect to claim 1.

With respect to Applicant's claim 20, the information storage portion is inseparable from the disposable test strip (see paragraph [0065]).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Ward (US 5,410,504).

The Groll reference, which was discussed in the 102(e) rejection above, fails to teach that the device uses impedance, wherein the electrically conductive elements of the information storage portion are either a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel.

Ward teaches a method of constructing a memory on a semiconductor substrate from a plurality of capacitor elements organized in a plurality of rows and columns, i.e.

in parallel. The capacitor array may be used for storing information, such as a ROM. Each capacitor is used to store one bit of information, wherein a capacitor storing a "1" will have a different capacitance than a capacitor storing a "0" (see Abstract; column 1, lines 63-68; column 2, lines 1-68; and column 3, lines 1-30).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll an array of capacitors arranged in parallel as taught by Ward because Ward teaches the benefit of creating a parallel capacitor array on a semiconductor substrate in order to create a memory that can be used for storing information, such as a ROM, wherein each capacitor is used to store one bit of information.

Claims 8 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Mandecki (US 2002/0006673).

Groll further fails to teach that the circuitry of the substrate of the device comprises a semiconductor portion and a non-volatile memory, wherein an electrical signal generator external to the device is configured to send an electrical signal to the non-volatile memory to cause storage of the information in the information storage portion.

Mandecki teaches transponders for use in methods of detecting biomolecules in a sample, wherein the transponders comprise a solid phase, a reagent or biomolecule binding element, and an index number or memory element that is electronically encoded on the transponder. The index number can be unique to each solid phase,

and is retrievable by a scanner device at any time during an assay. The index number can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay. The memory element can be encoded by a user just before, during or after a biological material is deposited on the surface of the transponder. The memory element is encoded with data sent by electromagnetic waves from a remote scanner read/write device, wherein the scanner read/write device further receives the encoded data transmitted by the transponder (see Abstract; and paragraphs [0007], [0009], [0021], [0027], [0031] and [0032]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll a memory element, wherein an external signal generator, i.e. scanner read/write device, is configured to send an electrical signal to the memory element to cause storage of information, as taught by Mandecki because Mandecki teaches the benefit of including a memory element on a transponder or solid phase device for detecting biomolecules in a sample, wherein the memory element can be encoded by an external scanner read/write device, in order to allow for encoding of the memory element by a user just before, during or after a biological material is deposited on the surface of the transponder. This encoding of the memory element allows for information to be stored within the transponder device for later retrieval, wherein the information can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay.



***Conclusion***

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Lai (US 2004/0029109) teaches a transponder for use in an assay of a substance, wherein the transponder comprises a biological substance and a read-only tag that contains encoded information (see Figure 1; and paragraphs [0017]-[0024] and [0066]); and

Bhullar et al. (US 6,814,844) teach a biosensor that comprises a support substrate, an electrochemical reagent, and a specific code pattern for identifying the biosensor (see Figures 1 and 2; and column 1, lines 47-55; column 2, lines 16-31; and column 5, lines 33-50).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/  
Examiner, Art Unit 1641

/Long V Le/  
Supervisory Patent Examiner, Art Unit 1641